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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,809	02/02/2005	Koji Kawai	TIP-04-1339	9964

35811 7590 07/06/2006

IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP  
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/520,809

Applicant(s)

KAWAI ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed **March 30, 2006** presents remarks and arguments to the office action mailed **January 05, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's election without traverse of the specie in the reply filed on 3/30/06 is acknowledged.

#### **Status of claims**

Claims 7-10 are cancelled.

Claims 11-19 are pending.

Claim 13 is withdrawn by examiner as it is to a non-elected specie.

#### ***Claim Objections***

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claims 11-14. See MPEP § 608.01(n). The claim has been treated to depend on claim 11. Applicant is advised to correct this if it is not so.

#### ***Claim Rejections - 35 USC § 103***

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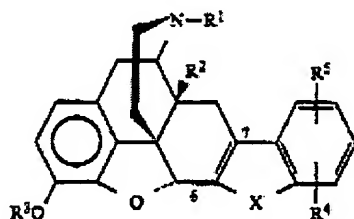
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portoghese et al. US 5, 352,680 in view of Rudd et al. Europ. J. Pharm.

Portoghese et al. teach a compound that is structurally identical to that of the



claimed compound as

(see col. 14, lines 10 +) as in

claims 11 and 12, where R<sup>1</sup> is an alkyl group having 1-5 carbon atoms, R<sup>2-4</sup> are

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hydrogen, or  $R^4$  and  $R^5$  together form an O, (as in claim 14)  $R^6$  is hydrogen and Q is



(see col. 14 lines 10-30).

With regards to claim 15, the above reference teaches, if a ligand acts at a single opioid receptor type or subtype, the potential side effects mediated through other opioid receptor types can potentially be minimized or eliminated, thus treating or preventing nausea and vomiting (see col. 1, lines 34-43) and the  $\mu$ -opioid agonist compound is a morphine (see col. 9 lines 8-17).

As to claim 17 and 19, the nausea or vomiting is caused by gastrointestinal dysfunction (characterized as smooth muscles of the gastrointestinal, biliary, and urinary tracts causing constipation, gallbladder spasm, and urinary retention) (see col. 1, lines 20-23).

Rudd et al. teach naltrindole (the drug name for the above compound) to inhibit the emetic reflex (vomiting) (see abstract and also page 82 (section 4.3 first para.)).

The instant invention differs from the disclosed by not particularly teaching nausea/vomiting resulting from postoperative sequelae.

Portoghese et al. teach the compound is an opioid antagonist and belongs to a group of morphinan derivatives.

One of ordinary skill in the art would have been motivated to administer the above compound to a patient wherein the nausea and vomiting is caused by postoperative sequelae (as in claim 18) since the compound as taught has the property

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of preventing vomiting/nausea as a whole, and would expect the drug to work since the action of is blocking of the stimulation of the emesis zone as it was found to be a member of the morphinan that prevents emetics.

It would therefore have been prima facie obvious to the skilled artisan at the time the invention was made to administer the drug for the treatment of nausea or vomiting as indicated by the above cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 6/24/06  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**